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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,914	12/27/2001	Birgit Linhart	0273-0006	6890

7590 10/17/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/026,914	**Applicant(s)** LINHART ET AL.	
	Examiner Ja-Na Hines	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *42,43 and 45-51*.
   Claim(s) withdrawn from consideration: *7,9,22-25,36-41 and 44*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

MARK NAVARRO
PRIMARY EXAMINER

The proposed after final amendment will not be entered because the amendment raises new issues that require further consideration and search. The new issues are drawn to the fusion polypetides now being drawn to timothy grass pollern allergens, instead of the previous generically claimed plant hybrids. Also, the claims are now drawn to testing the fusion polypeptide as a candidate immunotherapeutic agent by administering the polypeptide to an animal and selecting an immunotherapeutic that induces IgE-blocking antibodies and induce stronger immune responses as compared with the individual components or mixtures. Furthermore, the amendment is not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Therefore, the after final amendment will not be entered.

Many of applicants' arguments are drawn to the newly proposed amendments, however the arguments are not persaussive, since the amendments are not being entered. Furthermore, those arguments that are drawn to the proposed after final amendments will not be addressed.

The written description of claims 42-43, 45 and 50-51 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. The specification and claims lack sufficient written description of a method of preparing hybrid plant fusion polypeptides and the instantly claimed polypeptides or the pharmaceutical compositions comprising them. Applicants' urge that there is written description for the instantly claimed method. Applicants point to using purified recombinant timothy grass pollen allergens as the basis of their invention. However the claims do not require the use of timothy grass pollen allergens, rather the claims are generic and drawn to an unidentified polynucleotide encoding a plant fusion polypeptide. There is only a discussion of timothy grass pollen allergens, there is no discussion of the generic polynucleotide encoding a plant fusion polypeptide. Applicants' assert that specific allergen have been isolated and sequenced and that the instant invention teaches and claims a hybrid polypeptide comprising those allergens. However, the instant claims encompass significantly more than just the timothy grass pollen allergens or even a specific allergen. Only claims 46-48 and 51 specific timothy grass allergens. There is no limitation on which plant allergens nor do the claims only encompass the timothy grass allergens. The examples are limited to Phl p1,2, 5 and 6. The claims are significantly broader than applicants' contention and support. Thus the invention is drawn to absolutely any plant allergens and any modification or fragment, yet there is no written description of such hybrid polypeptides. Therefore, this argument is not persuasive, since it does not overcome the written description issue.

The new matter rejection of claims 42-43 and 48-51 under 35 U.S.C. 112, first paragraph, is maintained for the reasons already of record. However it appears that the entire specification appears to fail to recite support for the generically claimed hybrid polypeptides. There is teaching of a generic hybrid plant fusion polypeptide. Applicant has failed to point to a teaching associated with any isolated fragments or these fragments being comprised within a hybrid polypeptide. There is no teaching of a hybrid polypeptide comprising the generic components which induce an in vivo antibody response in any host. Therefore, applicants must specifically point to page and line number support for the identity of such generic hybrid polypeptides as recited by the new claims. Therefore, the claims incorporate new matter and the rejection is maintained since applicants' arguments are not persuasive.

The rejection of claims 45-51 under 35 U.S.C. 103(a) as being unpatentable over Ball et al., in view of Vrtala et al., is maintained for reasons already of record. Therefore it would have been prima facie obvious at the time of applicants' invention to modify the plant polypeptide as taught by Ball et al., to include a different plant allergen as taught by Vrtala et al., to create a hybrid plant fusion allergen wherein said allergen is a fusion protein of two or more timothy grass pollen allergens, since Ball et al., already teach the need to have a hybrid or fusion polypeptide. Ball et al., teach that plant allergenic proteins such as Phl pl are amenable to being comprised within fusion proteins and/or hybrid polypeptides and can be fused to any other polypeptide that can be expressed as a fusion protein in prokaryotic or eukaryotic cells, while Vrtala et al., teach polypeptides that can be expressed in prokaryotic or eukaryotic cells, thus no more than routine skill would have been required to create a hybrid polypeptide comprising at least two plant allergens. Thus, there is a reasonable expectation of success in using the Phl pl of Ball et al., and any other polypeptide such as the ones taught by Vrtala et al., when the prior art teaches that all of these plant allergens can be expressed as a fusion protein in prokaryotic or eukaryotic cells.